



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup>:

A61N 5/02

A1

(11) International Publication Number:

WO 97/30752

(43) International Publication Date:

28 August 1997 (28.08.97)

(21) International Application Number: PCT/US96/02663

(22) International Filing Date: 26 February 1996 (26.02.96)

(71) Applicant: LASERSIGHT, INC. [US/US]; Suite 160, 12249  
Science Drive, Orlando, FL 32826 (US).(72) Inventor: LIN, Jui-Teng; 730 Willow Run Lane, Winter  
Springs, FL 32708 (US).(74) Agent: HOBBY, William, M., III; Hobby & Beusse, Suite 375,  
157 East New England Avenue, Winter Park, FL 32789  
(US).

(81) Designated States: AL, AU, BB, BG, BR, CA, CN, CZ, EE, FI, GE, HU, IS, JP, KP, KR, LK, LR, LT, LV, MG, MK, MN, MX, NO, NZ, PL, RO, SG, SI, SK, TR, TT, UA, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG); Eurasian patent (AZ, BY, KG, KZ, MD, RU, TJ, TM); European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE); OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

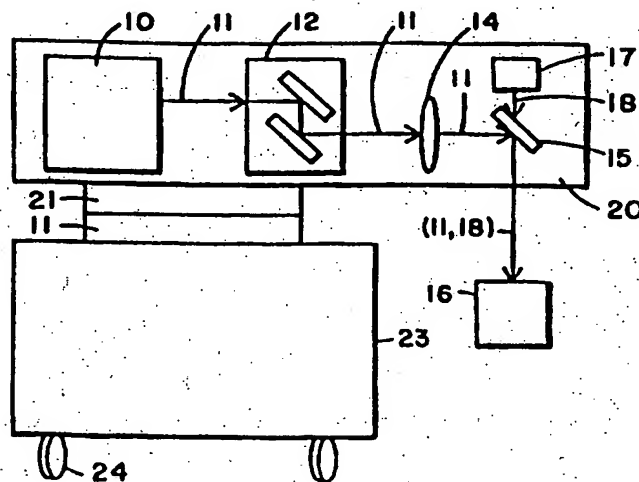
Published

With international search report.

(54) Title: NON-CONTACT SCANNING LASER SYSTEM

## (57) Abstract

A refractive laser system is disclosed for use in refractive laser surgery and is a compact, low cost ophthalmic laser system (10, 35) which has computer controlled scanning for a non-contact delivery device for both photo-ablation and photo-coagulation in corneal reshaping. The advantages of the non-contact, scanning device (12, 37) used in the process include being safer, reduced cost, more compact and more precise. Lasers are selected with energies of 0.01-10 mJ, repetition rates of 1-10,000, pulse duration of 0.01 nanoseconds to a few hundreds of microseconds, and with spot sizes of 0.05-2 mm.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

## NON-CONTACT SCANNING LASER SYSTEM

1     BACKGROUND OF THE INVENTION2     1. Field of the Invention

3         The present invention relates to laser ophthalmic  
4     surgery using a compact, low-cost, low-power laser  
5     system with a computer-controlled, non-contact process  
6     and corneal topography to perform corneal reshaping  
7     using either surface ablation or thermal coagulation.  
8     This application is a continuation-in-part application  
9     of Serial No. 07/985,617, filed December 3, 1992.

10

11

12     2. Prior Art

13         Various lasers have been used for ophthalmic  
14     applications including the treatments of glaucoma,  
15     cataract and refractive surgery. For non-refractive  
16     treatments (glaucoma and cataract), suitable laser  
17     wavelengths are in the ranges of visible to near  
18     infrared. They include : Nd:YAG (1064 nm), doubled-YAG  
19     (532 nm), argon (488, 514 nm), krypton (568, 647 nm),  
20     semiconductor lasers (630-690 nm and 780-860 nm) and  
21     tunable dye lasers (577-630 nm). For refractive  
22     surgeries (or corneal reshaping), ultraviolet (UV)  
23     lasers (excimer at 193 nm and fifth-harmonic of Nd:YAG  
24     at 213 nm) have been used for large area surface  
25     corneal ablation in a process called photorefractive  
26     keratectomy (PRK). Corneal reshaping may also be  
27     performed by laser thermal coagulation currently  
28     conducted with Ho:YAG lasers using a fiber-coupled,  
29     contact-type process. However, the existing  
30     ophthalmic lasers as above described have one or more  
31     of the following limitations and disadvantages: high

1 cost due to the high-power requirement in UV lasers  
2 for photorefractive keratectomy; large size and  
3 weight; high maintenance cost and gas cost (for  
4 excimer laser), and high fiber-cost for contact-type  
5 laser coagulation.

6 In light of the above, it is an object of the  
7 present invention to provide ophthalmic laser systems  
8 which offer the advantages of: low-cost, reduced size  
9 and weight, reliability, easy-operation and reduced  
10 maintenance. Another object of this invention is to  
11 provide a computer-controlled scanning device which  
12 enables use of a low-cost, low-energy laser for  
13 photorefractive keratectomy currently performed only  
14 by high-power UV lasers.

15 It is yet another object of the present invention  
16 to provide a refractive laser system which is compact,  
17 portable and insensitive to environmental conditions  
18 (such as vibration and temperature). This portable  
19 system may also be used for a mobile clinical center  
20 where the laser is transported by a van. It is yet  
21 another objective of the present invention to provide  
22 a non-contact process for corneal reshaping using  
23 laser thermal coagulation, where predetermined corneal  
24 correction patterns are conducted for both spherical  
25 and astigmatic changes of the corneal optical power.

26 The prior U.S. Patent No. 4,784,135 to Blum, et  
27 al. and assigned to IBM teaches the first use of far  
28 ultraviolet irradiation of a biological layer to cause  
29 ablative photodecomposition. This patent teaches that  
30 using a laser beam housing a wavelength of 193 nm and  
31 an energy level of much greater than 10mJ/cm<sup>2</sup>/pulse can  
32 be used to photoablate corneal tissue without the  
33 build up of excess heat. The present invention on the  
34 other hand uses a process that allows the use of

1 energy levels of less than 10 mJ/pulse in a process  
2 that still allows photoablation.

3 There are several prior art U.S. Patents relating  
4 to refractive surgery, or photorefractive keratectomy.  
5 A UV solid-state fifth-harmonic of Nd:YAG (or Nd:YLF)  
6 laser at 213 nm (or 210 nm), is disclosed in U.S.  
7 Pat. No. 5,144,630 by the inventor, J.T. Lin. U.S.  
8 Pat. No. 4,784,135 suggests the use of a UV laser with  
9 wavelengths less than 200 nm, in particular Argon  
10 Fluoride (ArF) laser at 193 nm, for non-thermal photo-  
11 ablation process in organic tissue. Devices for beam  
12 delivery and methods of corneal reshaping are  
13 disclosed in U.S. Pat. No. 4,838,266 using energy  
14 attenuator, and U.S. Pat. No. 5,019,074 using an  
15 erodible mask. Techniques for corneal reshaping by  
16 varying the size of the exposed region by iris or  
17 rotating disk are discussed in Marshall et al,  
18 "Photoablative Reprofilng of the Cornea Using an  
19 Excimer Laser: Photorefractive Keratectomy" Vol. 1,  
20 Lasers in Ophthalmology, pp. 21-48 (1986). Tangential  
21 corneal surface ablation using ArF excimer laser or  
22 harmonics of Nd:YAG laser (at 532 and 266 nm) is  
23 disclosed in U.S. Pat. No. 5,102,409.

24 This prior art however requires high UV energy of  
25 (100-300 mJ) per pulse from the laser cavity or  
26 (30-40) mJ per pulse delivered onto the corneal  
27 surface, where large area corneal ablation using a  
28 beam spot size of about (4-6) mm which gives an energy  
29 density of (120-200) mJ/cm<sup>2</sup>. Moreover, the prior art  
30 Argon Fluoride excimer lasers operate at a repetition  
31 rate of (5-15) Hz and also limit the practical use of  
32 the tangential ablation concept which takes at least  
33  
34

1 (5-10) minutes for a -5 diopter corneal correction in  
2 a 5-mm optical zone. The high energy requirement of  
3 the currently used Argon Fluoride excimer laser  
4 suffers the problems of: high-cost (in system,  
5 erodible mask and gas cost), high-maintenance cost,  
6 large size/weight and system are sensitive to  
7 environmental conditions (such as temperature and  
8 moisture).

9 The prior L'Esperance patent, US Pat. No.  
10 4,665,913, disclosed the method of a scanning laser  
11 for corneal reshaping. The proposed concept of this  
12 prior art, however, had never been demonstrated to be  
13 practical or to achieve the desired clinical  
14 requirement of smooth ablation of the corneal surface.  
15 This prior art is not practically useful and had not  
16 ever been demonstrated to be real because of the  
17 conditions in the art. A high-power laser of (100-200  
18 mJ) is required in the prior art in order to obtain a  
19 useful beam with a substantially square spot size of  
20 0.5x0.5 mm (see prior art, Col. 3, line 65 and Col. 4,  
21 lines 1-14) due to the low efficiency of obtaining  
22 such a beam, and which further requires a  
23 substantially uniform density (see Col. 13, line 30  
24 and Col. 15, line 25). To achieve myopic correction,  
25 for example, the prior art (Col. 13, lines 61-66 and  
26 Col. 15 lines 60-65) proposes a smooth laser density  
27 increase with increasing scanning radius under the  
28 condition that a substantially uniform density of the  
29 scanning beam is required for a substantially uniform  
30 scan area (Col. 15, lines 20-28 of L'Esperance).  
31 Furthermore, L'Esperance teaches (Col. 4, lines 40-50)  
32 that a depth of 0.35 mm in an area of 6 mm diameter  
33 might be achieved in about 15 seconds when a beam spot  
34 of 0.5x0.5 mm is used and each pulse ablated 14

1 microns. The prior art proposes the method of having  
2 individual square beams (0.5x0.5 mm) scan to the  
3 fashion of exact matching of the square boundaries to  
4 cover the area of 6 mm, where the overlap among these  
5 individual beams should be avoided, otherwise  
6 excessive ablation near the boundaries of each 0.5x0.5  
7 mm spot causes ridges. This is also part of the  
8 reason that the prior art requires a substantially  
9 square section of the individual beam with a  
10 substantially uniform density.

11 The L'Esperance patent No. 4,665,913 requires a  
12 complex apparatus to select a section of the beam  
13 which is substantially uniform in density within a  
14 substantially square spot "dot". The overall  
15 efficiency would be less than 10% from the output of  
16 the laser window to the corneal surface and requires,  
17 where a high power (at least 100 mJ) excimer laser  
18 than will be required than the Blum, et al. patent.  
19 It is almost impossible to match exactly the boundary  
20 of each square beam to achieve a substantially uniform  
21 scanned area even if each individual beam is perfectly  
22 uniform and square in shape and the smooth increase of  
23 the radius of scanned areas to obtain, for example, a  
24 myopic correction profile, would still be almost  
25 impossible to achieve for an overall smooth corneal  
26 surface. The successive sweep of the scan areas would  
27 always leave ridges between these sweeps. It should  
28 also be noticed that in L'Esperance's patent (Col. 18,  
29 lines 10-28) uses overlaps between each of the scanned  
30 areas to obtain the desired ablation profiles of  
31 myopic (or other) corrections. However, the ridges  
32 between each of the successive ablated areas are very  
33 difficult to avoid if within each scanned area the  
34 ablated profiles are not substantially uniform. In

1 fact, one should expect a very rough surface on these  
2 ablated areas in addition to the regular ridges  
3 between each overlapped zones. One of the problems  
4 found in these teachings is that each required  
5 individual ablated area be substantially uniform and  
6 in a round or square shape, which is very difficult to  
7 achieve even if a perfectly uniform, square portion of  
8 a fundamental beam is produced using a complex  
9 apparatus for beam reshaping and having the high  
10 initial power.

11 It is not clear that L'Esperance has found a  
12 suitable scanning method or an effective method of  
13 selecting a perfect beam (with uniform density and  
14 well-defined shape) which would overcome the  
15 above-described difficulties and make the proposed  
16 teaching become practical in cost and design for any  
17 clinical uses. In fact, L'Esperance's scanning method  
18 has also been challenged by another prior art of  
19 Muller, US Pat. No. 4,856,513, where the difficulties  
20 and problems of L'Esperance's teachings are discussed  
21 (see Col. 2, lines 1-40 of Muller's patent).

22 It is therefore a further object of the present  
23 invention to provide a method and apparatus for  
24 corneal reshaping by using software-driven new  
25 scanning patterns which do not require substantially  
26 uniform density or a specific spot shape. Contrary to  
27 L'Esperance's teachings, which suggest that there  
28 should be a perfect boundary match among each square  
29 beams and that excessive overlap should be avoided,  
30 the present invention proposes that a large portion  
31 (50%-80%) of overlap among the individual beams is  
32 necessary in order to achieve uniform ablated areas  
33 and a smooth profile without ridges. Furthermore, a  
34 low-power UV laser (0.1-2 mJ on corneal surface) at



1 its bare-beam (having typically a 3-lop profile)  
2 without any beam reshaping is sufficient to achieve a  
3 smooth ablation surface based on the method proposed  
4 in the present invention, where computer-controlled  
5 beam overlap and orientation are employed. In  
6 addition to the surface quality problems, it is also  
7 impossible for L'Esperance to achieve any meaningful  
8 clinical results using his proposed techniques based  
9 on the present low-energy laser of (2-4) mJ from the  
10 output laser window and (0.1-2) mJ on corneal surface.

11 Therefore, another object of the present  
12 invention is to provide a new method of beam scanning  
13 which combines beam overlap and orientation for a  
14 random beam density distribution on the ablated  
15 corneal surface such that the individual beam profiles  
16 are not critical, where the focused beam (spot size of  
17 0.1- 1.2 mm) uses very low energy (0.1-2 mJ) and at  
18 its bare-profile is delivered onto the corneal surface  
19 in an averaged fashion. Uniform, near flat-top  
20 ablated areas of (1-9 mm in diameter) can be performed  
21 by the nonuniform starting-beam, but only when a set  
22 of specific predetermined overlap and orientation  
23 parameters are used. Portions of the theoretical  
24 background was published by the inventor, J. T. Lin,  
25 in SPIE Pro. vol 1644, Ophthalmic Technologies II  
26 (1991), p.p. 266-275.

27 One of the essential feature of the present  
28 invention for the photorefractive keratectomy process  
29 is to use a scanning device in a laser system which  
30 has high repetition rates, 50 to 50,000 Hz, but  
31 requires less energy, ranging between 0.05-10 mJ per  
32 pulse, or about 10 to 100 times less than that of the  
33 prior art. This new concept enables one to make the  
34 refractive lasers at a lower cost, smaller size and

1 with less weight (by a factor of 5-10) than that of  
2 prior art lasers. Furthermore, these compact lasers  
3 of the present invention are portable and suitable for  
4 mobile clinical uses. To achieve beam uniformity and  
5 fast refractive surgery (30 to 60 seconds), a  
6 mathematical model of the beam overlap and ablation  
7 speed is also disclosed in the present invention.

8 For the laser thermo-keratoplasty (LTK) process,  
9 the prior art uses fiber-coupled contact-type  
10 procedure which involves the following drawbacks: (i)  
11 slow processing speed (typically a few minutes to  
12 perform eight-spot coagulation) which causes the  
13 non-uniform collagen shrinkage zone; (ii) circular  
14 coagulation zone which limits the procedure only for  
15 spherical type correction such as hyperopia; and (iii)  
16 the contact fiber-tip must be replaced in each  
17 procedure.

18 In the present invention, a computer-controlled  
19 scanning device is able to perform the laser  
20 thermokeratoplasty procedure under a non-contact mode  
21 and conduct the procedure many times faster than that  
22 of the prior contact-procedure and without cost for a  
23 fiber-tip replacement. Furthermore the coagulation  
24 patterns can be computer predetermined for specific  
25 applications in both spherical and astigmatic  
26 corrections. The flexible scanning patterns will also  
27 offer uniform and predictable collagen shrinkage.

28 For ophthalmic applications, it is another  
29 objective of the present invention to include but not  
30 limited to photorefractive keratectomy, laser  
31 thermokeratoplasty, epikeratoplasty, intrastroma  
32 photokeratectomy (IPK), phototherapeutic keratectomy  
33 (PTK), and laser-assisted keratomileusis (LAK).

1     SUMMARY OF THE INVENTION

2             The preferred embodiments of the basic ophthalmic  
3 surgery method uses a laser system for the ophthalmic  
4 surgery process, including: (1) a diode-pumped  
5 solid-state lasers of Nd:YAG or Nd:YLF which is  
6 frequency-converted by nonlinear crystals of KTP  
7 (potassium titanyl phosphate), LBO (lithium  
8 triborate), KNbO<sub>3</sub> (potassium niobate) and BBO (beta  
9 barium borate) into the fifth-harmonic at wavelength  
10 of 213 nm or 210 nm with energy of 0.01 to 5.0 mJ; (2)  
11 a compact, low-cost, low-power (energy of 1 to 10 mJ  
12 per pulse) argon fluoride excimer laser at 193 nm; (3)  
13 a frequency-converted Alexandrite or Li:SAF or diode  
14 lasers at (193-220) nm; (4) a compact, low-cost,  
15 Q-switched Er:YAG laser at 2.94 microns; (5) a  
16 free-running Ho:YAG (at 2.1 microns) or Er:glass (at  
17 1.54 microns) or diode laser (1.9-2.5 microns); (6)  
18 ultrashort pulse IR laser (750-1100 nm) and (7) mid-IR  
19 (2.5-3.2 microns) laser generated from optical  
20 parametric oscillation.

21             According to one aspect of the present invention,  
22 the above-described basic lasers includes UV-lasers  
23 (193-215 nm) and IR-laser (1.5-3.2 microns) which are  
24 focused into a spot size of (0.05-2) mm in diameter,  
25 where laser energy per pulse of (0.01-10) mJ is  
26 sufficient to achieve the photo-ablation threshold  
27 (PAT) energy density of 50 to 600 mJ/cm<sup>2</sup> depending upon  
28 the laser parameters (wavelengths and pulse duration)  
29 and tissue properties (absorption and scattering).  
30 The prior art excimer laser uses large beam spot  
31 ablation (4-6 mm) and require much higher laser energy  
32 (100-300 mJ) than the low-power lasers presented in  
33 this invention. In the present invention, a scanning,  
34 non-contact device is used to control the low-power

10.

1 laser for corneal diopter change, whereas diaphragms  
2 or masks are used in the high-power, high-cost excimer  
3 lasers, and contact, fiber-tip is used in the  
4 photo-coagulation procedure.

5 In another aspect of the present invention, a  
6 mathematical model is presented according to the  
7 optimal beam overlap for beam uniformity and fast  
8 procedure and scanning patterns for refractive  
9 corrections of myopia, hyperopia and astigmatism. For  
10 high-repetition lasers (50 to 5,000 Hz as proposed  
11 herein), refractive procedures may be completed in 20  
12 to 60 seconds (depending on the diopter corrections)  
13 in the present invention, where scanning speed is only  
14 limited by the laser repetition rates.

15 A three-dimensional translation device (in X, Y  
16 and Z) is integrated into the above laser systems,  
17 where the laser heads are compact and light-weight and  
18 can be steered to the corneal center by the  
19 translation stages. The prior art high-powered excimer  
20 laser systems are stationary and require a motorized  
21 chair for corneal concentration. Beam steering and  
22 scanning is very difficult for these high-power,  
23 heavy-weight excimer lasers.

24 In yet another aspect of the present invention,  
25 a free-running Ho:YAG ( at 2.1 microns) or Er:glass  
26 (at 1.54 microns) or diode (1.9-3.2 microns) laser  
27 delivers a beam by a fiber waveguide and coupled to a  
28 scanning device for non-contact procedure for laser  
29 thermokeratoplasty (LTK), where optimal scanning  
30 patterns for corneal coagulation are performed for  
31 both spherical and astigmatic corrections.

32 In yet another aspect of the present invention,  
33 the above-described laser system provides an  
34 effective, low-cost tool for procedures of synthetic

1 epikeratoplasty (SEK), where the artificial lens is  
2 sculpted with the laser to optimize lens curvature  
3 without causing problems of corneal haze and  
4 corrective regression. Real corneal tissues may also  
5 be sculpted and implanted by the above-described laser  
6 systems, a procedure known as laser myopic  
7 keratomileusis (MKM). Furthermore the UV and IR lasers  
8 disclosed in the present invention provide an  
9 effective tool for phototherapeutic keratectomy (PTK)  
10 which is currently conducted by high-power excimer  
11 lasers and the procedure conducted by diamond-knife  
12 called radial keratotomies (RK). This procedure  
13 conducted by UV or IR lasers is called laser radial  
14 keratotomy (LRK). The fundamental beam at 1064 or  
15 1053nm wavelength of the present invention may also be  
16 used for the intrastroma photorefractive keratectomy  
17 (IPK), where the laser beam is focused into the  
18 intrastroma area of the corneal and collagen tissue  
19 are disrupted.

20 The ophthalmic applications of the laser systems  
21 described in the present invention should include  
22 photorefractive keratectomy, phototherapeutic  
23 keratectomy, laser thermokeratoplasty, intrastroma  
24 photokeratectomy, synthetic epikeratoplasty, and  
25 laser radial keratotomy.

26

#### 27 BRIEF DESCRIPTION OF THE DRAWINGS

28 Fig. 1 is a block diagram of computer-controlled  
29 laser system consisting of a laser, scanning device,  
30 power supply and the beam steering stage for  
31 ophthalmic applications;

32 Fig. 2 is a block diagram for the generation of  
33 ultraviolet wavelengths at 213 nm or 210 nm using  
34 nonlinear crystals in a diode-pumped system;

1        Fig. 3 is a block diagram of a  
2 computer-controlled refractive laser system of Ho:YAG  
3 or Er:glass or diode laser in a non-contact scanning  
4 mode for laser thermokeratoplasty;

5        Figs. 4A through 4E shows computer-controlled  
6 scanning patterns for photo-coagulation in non-contact  
7 LTK procedures for both spherical and astigmatic  
8 corneal reshaping;

9        Figs. 5A and 5B are procedures for laser-assisted  
10 myopic keratomileusis and hyperopic keratomileusis,  
11 where the reshaping can be performed either on the  
12 inner or outer part of the tissue;

13        Figs. 6A through 6D show computer-controlled beam  
14 overlap and scanning patterns for myopic, hyperopic  
15 and astigmatic correction using UV (193-240 nm) or IR  
16 (0.7-3.2 microns) lasers;

17        Figs. 7A and B are laser radial keratectomy  
18 patterns (LRK) using laser excisions for myopia  
19 (radial-cut) and astigmatism (T-cut);

20        Figs. 8A through 8D show ablation patterns for  
21 refractive correction using predetermined coatings on  
22 UV or IR grade windows;

23        Figs. 9A through 9B show the spatial overlap for  
24 uniform pattern;

25        Figs. 10A through 10B show the beam orientation  
26 for smooth ablation; and

27        Fig. 11 shows the oriented expanding scanning to  
28 achieve the required ablation profiles, where the  
29 diameters are governed by a mathematical formula.

30

### 31        DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

32        The theoretical background of the present  
33 invention with regards to the beam overlap and  
34 ablation rate in photorefractive keratectomy,

1    intrastroma            photokeratectomy,            synthetic  
2    epikeratoplasty,       phototherapeutic keratectomy and  
3    myopic keratomileusis procedures described in the  
4    present invention is as follows.

5        Given a laser energy per pulse of  $E$  (in mJ), an  
6    intensity of  $I$  (in mJ/cm<sup>2</sup>) may be achieved by focusing  
7    the beam into an area of  $A$ , where  $I=E/A$ . For corneal  
8    tissue ablation to occur requires the laser intensity  
9    ( $I$ ) to be above the photoablation threshold (PAT),  
10    (60-120) mJ/cm<sup>2</sup> for UV-laser (193-215 nm) and (200-600)  
11    mJ/cm<sup>2</sup> for IR-laser (2.5-3.2 microns). Therefore it is  
12    always possible to tightly focus a laser beam and  
13    achieve the PAT value even for a low-energy laser  
14    (0.1-5) mJ. The drawback of using a low-energy,  
15    small-spot laser for large area ablation is that the  
16    operation time will be longer than that of a  
17    large-spot but high-power laser. However, time of  
18    operation may be shortened by using a  
19    high-repetition-rate laser (higher than 50 Hz).  
20    Small-spot, low-energy lasers for large area surface  
21    ablation would become practical only when a scanning  
22    device is used in a high-repetition-rate laser and  
23    only when uniform beam profile can be assured by the  
24    appropriate beam overlap. These two important issues  
25    are addressed in the present invention.

26        The overall operation rate ( $R$ ) for a given  
27    diopter correction ( $D$ ) is limited by the laser  
28    scanning rate ( $R_1$ ) which is in turn limited by the  
29    laser repetition rate. In addition,  $R$  is also  
30    proportional to the tissue ablation rate ( $R_T$ ) which is  
31    proportion to the laser intensity  $I$  (or energy  
32    density) at a given energy  $E$ .

33        The diopter change ( $D$ ) in the case of myopia is  
34    related to the correction zone diameter ( $W$ ) and the

1 center ablation thickness ( $h_0$ ) and the ablation  
2 profile  $h(x)$  (at corneal position  $x$ ) by:

3 
$$h(x) = h_0 + 1.32DX^2 \quad (1)$$

4 
$$h_0 = -0.3315DW^2 \quad (2)$$

5 In a scanning system as disclosed in the present  
6 invention, the number of ablation layers ( $M_1$ ) (without  
7 beam overlap) required for D-diopter correction is  
8 therefore related to the ablation thickness per pulse  
9 ( $T_1$ ),  $D$ , and  $W$  by

10 
$$M_1 = h_0/T_1 = -0.3315DW^2/T_1 \quad (3)$$

11 To include the overlap factor ( $F$ ),  $F=2$  for a 50% beam  
12 overlap scan and  $F=5$  for 80% overlap, the required  
13 effective number of overlapped ablation layers is  
14  $M_1/F$ .

15 For a given ablation zone of  $W$  and laser focused  
16 spot area of  $A$ , one requires an effective single-layer  
17 scanning time ( $TS$ ) of  $FW^2/A$ .

18 The total operation time ( $T$ ) needed for  $h_0$  center  
19 ablation or D-diopter correction becomes

20 
$$T = (M_1/F) (TS) DW^4/E \quad (4)$$

21 
$$T = DW^4/E$$

22 Equation 4 gives us the scaling-law for operation  
23 time required ( $T$ ), the laser energy ( $E$ ), diopter  
24 change ( $D$ ) and the ablation zone diameter ( $W$ ). For a  
25 given laser energy per pulse of  $E$ , the overall  
26 operation rate ( $1/T$ ) is independent to the laser  
27 intensity ( $I$ ) and beam spot size ( $A$ ). By increasing  
28 the laser average-power ( $P$ ), defined by laser  
29 energy/pulse  $\times$  repetition rate, more total energy may  
30 be delivered to the cornea per unit time. The  
31 average-power ( $P$ ) is the key factor which actually  
32 determine the overall operation rate (or time)  
33 required to achieve the diopter change. By realizing  
34 that the scanning rate ( $1/TS$ ) is proportional and



1     synchronized to the laser repetition rate (RP), we are  
2     able to re-express Equation (4) as

3              $T = DW^4/P$                              (5).

4             It is important to note that given an  
5     average-power of P, the laser intensity must be above  
6     the photo-ablation threshold(PAT) by either beam  
7     focusing or increase the laser energy.

8             Based upon the above-described theory, some  
9     important features are: (i) CW lasers (either UV or  
10    IR) with low intensity normally can not cause  
11    photo-ablation since the energy density is lower than  
12    the PAT value; (ii) Lasers (UV or IR) at Q-switched or  
13    mode-locked mode and with pulse-duration shorter than  
14    100 nanosecond will normally achieve the intensity  
15    above the PAT even at low-energy level of

16    0.05-5 mJ. In particular, picosecond lasers at high  
17    repetition rate is desirable where energy in the  
18    microjoule range would be sufficient. Moreover, the  
19    Q-switched short pulse lasers have smaller thermal  
20    damage than that of free-running lasers. The

21    cost-effective refractive lasers are those which have  
22    high repetition rate (50 Hz and up) but operated at  
23    low-energy (0.05-5 mJ) and short pulse duration  
24    (0.001-20 nanoseconds). The preferred embodiments

25    disclosed in the present invention as discussed in  
26    Fig. 1 are based upon this theory. Beam focusing and  
27    scanning are always required to achieve the PAT and  
28    smooth ablation profile. The individual beam profile  
29    in the scanning system is not as critical as that in  
30    prior art lasers which require a uniform overall  
31    profile within the large ablation zone of (4-6) mm.

32    In laboratory tests, we have achieved a very smooth  
33    ablation profile with zone diameter up to 8 mm  
34    starting from a non-uniform focused beam profile which

1 was randomly scanned over the ablation zone of (1-8)  
2 mm. Using overlap of (50-80)% of focused beam spot of  
3 (0.2-1.5) mm, and a typical number of pulses delivered  
4 to the corneal surface of 2,000-4,000, which assures  
5 a sufficient beam overlap for smooth profile and  
6 pulse to pulse energy fluctuation is not critical.

7 Referring to Fig. 1, a refractive laser system in  
8 accordance with the present invention comprises a  
9 basic laser 10 having UV (193-220 nm) or IR (0.7-3.2  
10 microns) wavelength 11 coupled by a scanning device 12  
11 having the beam from focusing optics 14 directed onto  
12 a reflecting mirror 15 into target 16 which target may  
13 be the cornea of an eye. An arming system 17 has a  
14 visible wavelength (from a laser diode or He-Ne laser)  
15 18 adjusted to be collinear with the ablation beam 11  
16 and defines the centration of the beam onto the cornea  
17 surface at normal incident. The basic laser head 20 is  
18 steered by a motorized stage for X and Y horizontal  
19 directions 21 and the vertical (height) direction 22  
20 which assures the focusing beam spot size and the  
21 centration of the beam onto the cornea. The system has  
22 a computer controlled panel 23 and wheels 24 for  
23 portable uses. The target 16 includes a human cornea  
24 for applications of photorefractive keratectomy,  
25 phototherapeutic keratectomy and laser radial  
26 keratotomy (using the UV 193, 210, 213 nm or IR 2.9  
27 microns beam focused on the corneal surface area) and  
28 intrastroma photokeratectomy (using the 1064 or 1053  
29 or 1047 nm beam, or their second-harmonic, focused  
30 into the intrastroma area), and synthetic or real  
31 corneal tissues for applications of synthetic  
32 epikeratoplasty and myopic keratomileusis. The  
33 computer controlling panel 23 also provides the  
34 synchronization between the scanning gavo

1 (galvanometer scanner) and the laser repetition rate.  
2 A commercially available galvanometer scanner made by  
3 General Scanning, Inc. is used in scanning the laser  
4 beam.

5 The laser systems described herein have been  
6 demonstrated using photorefractive keratectomy  
7 procedure with a diopter corrections up to -6 in PMMA  
8 plasty and -12 in corneal tissues. In the case of  
9 PMMA, we have also measured the diopters by a  
10 lensmeter with well-defined readings in the ranges of  
11 -1 to -12 diopters. This data provides the evidence of  
12 predictable diopter corrections using the laser  
13 systems of the present invention. Furthermore,  
14 minimal tissue thermal damage of 0.3-1.0 microns were  
15 measured by TEM (transmission electron microscopy). In  
16 measurements, a multi-zone (MZ) approach for  
17 high-diopter corrections (8-12) was used, where the  
18 center zone is 3 mm and the correction power decreases  
19 when the zone increases from 4 mm to 6 mm. This multi-  
20 zone approach reduces the overall ablation thickness  
21 and hence reduces the haze effect.

22 Still referring to Fig. 1, the basic laser 10,  
23 according to the present invention, includes a  
24 compact, optically-pumped (either flash-lamp or  
25 laser-diode pumped) lasers of Nd:YAG, Nd:YLF or the  
26 self-frequency-doubling crystal of NYAB (neodymium  
27 yttrium aluminum) with pulse duration of 0.05-20  
28 nanoseconds and repetition rate of 1-10,000 Hz. It is  
29 known that this basic laser 10 is available using a  
30 standard Q-switch or mode-lock, where the UV  
31 wavelength at 209-213 nm may be achieved by the  
32 frequency conversion techniques using nonlinear  
33 crystals disclosed by the inventor in U.S. Pat. No.  
34 5,144,630. The UV laser energy required for efficient

1 ablation ranges from 0.01 mJ to 5 mJ. The basic laser  
2 also includes a compact, argon fluoride excimer laser  
3 (at 193 nm) with repetition rate of (1-1,000) Hz,  
4 energy per pulse of (0.5-10) mJ, pulse duration of  
5 (1-50) nanoseconds and a compact, Er:YAG laser (at  
6 2.94 microns) with repetition rate of (1-200) Hz,  
7 energy per pulse of (50-500) mJ, pulse duration of  
8 (50-400) nanoseconds and frequency-converted IR lasers  
9 of diode laser, optically-pumped Alexandrite or Li:SAF  
10 lasers, where efficient nonlinear crystals (as shown  
11 in Fig. 2) may be used to convert the fundamental  
12 wavelength (770-880 nm) into its fourth-harmonic at  
13 the UV tunable wavelength of (193-220 nm) with energy  
14 of (0.01-5.0) mJ, repetition rate of (1-10,000) and  
15 pulse duration of (0.05-50) nanoseconds. Only two  
16 nonlinear crystals are needed in this case and overall  
17 efficiency is higher than that of the fifth harmonic  
18 generation which requires three nonlinear crystals.  
19 The basic laser may also include ultrashort pulsed  
20 lasers, such as a commercialized mode-locked  
21 Ti:sapphire laser or other solid-state laser, with  
22 wavelength ranges of (750-1100 nm), repetition rates  
23 of (0.01-100 MHz), energy per pulse of (0.01-100)  
24 microjoules, and pulse durations of (0.05-10)  
25 picoseconds where focused beam spot size of (0.05-0.5)  
26 mm is required to achieve the ablation threshold.  
27 When using an ultrashort pulse laser with very high  
28 peak power density (gigawatts range), the tissue  
29 ablation should be insensitive to laser wavelengths  
30 since the tissue ablation is assisted by the plasma-  
31 enhanced absorption with minimal tissue thermal  
32 damage. A focused spot size of (0.05-0.5) mm of the  
33 ultrashort pulsed lasers would be appropriate to  
34 achieve the tissue ablation and precise ablation

1 profile is available by the scanning device proposed  
2 by the present invention. Without a scanning device,  
3 an ultrashort pulsed laser cannot be used in  
4 refractive surgery due to its energy level of less  
5 than 0.1 mJ and spot size smaller than 0.5 mm. The  
6 above-described lasers may also be frequency-converted  
7 into UV ranges of (190-220) nm suitable for  
8 photoablation.

9 The basic laser also includes a mid-IR (2.5-3.2  
10 microns) laser generated from optical parametric  
11 oscillation (OPO) using a near-IR laser (such as  
12 Nd:YAG or Nd:YLF, flash-lamp or diode-pumped) as the  
13 pumping sources and KTP or BBO as the frequency  
14 conversion crystals. The OPO laser has advantages  
15 over the Q-switched Er:YAG laser, including higher  
16 repetition rate (10-5,000 Hz) and shorter pulse width  
17 (1-40 n.s.). These advantages provide faster surgical  
18 procedure and reduced thermal damage on the ablated  
19 corneal tissue. Typical energy per pulse of the OPO  
20 laser is (0.1-10) mJ. Greater detail on OPO was  
21 published by the inventor in Optical Communications,  
22 vol. 75, p. 315 (1990).

23 Still referring to Fig. 1, the scanning device 12  
24 is synchronized with the laser repetition rate, where  
25 the computer software is capable of providing  
26 predetermined patterns according to a patient's  
27 corneal topography for the corrections of myopia,  
28 hyperopia and astigmatism. Astigmatic correction, in  
29 particular, is difficult to perform in prior art  
30 systems using a non-scanning diaphragm but can be  
31 easily achieved by the present invention using a  
32 scanning device. Furthermore, a multi-zone procedure  
33 for high diopter (6-15) changes can be performed by  
34

1 the computer program rather than that of the  
2 conventional mechanical iris.

3 The low-power laser systems described in the  
4 present invention can perform the procedures normally  
5 required in high-power lasers because a scanning  
6 device is used to assure the uniform corneal ablation  
7 by beam overlap and the ablation threshold is  
8 achievable by small spot size.

9 Referring to Fig. 2, a preferred embodiment for  
10 the basic laser 10 of Fig. 1 having a UV wavelength  
11 includes a diode-pumped Nd:YAG (or Nd:YLF) 25 having  
12 a fundamental wavelength of 1064 nm (or 1047 and 1053  
13 nm) 26 and is focused by a lens 27 into a doubling  
14 crystal 28 (KTP, KNbO<sub>3</sub>, LBO or BBO) to generate a  
15 green wavelength 30 at 532 nm (or 524 and 527 nm).  
16 The green beam 30 is further converted by a fourth  
17 harmonic crystal 31 (BBO) to generate a UV wavelength  
18 32 at 266 nm (or 262-263 nm) which is finally  
19 converted by a fifth harmonic crystal 33 to generate  
20 the UV wavelength 11 at 213 nm (or 209-211 nm). From  
21 a commercially available diode-pumped Nd:YLF laser I  
22 am able to achieve the UV (at 209-211 nm) energy of  
23 0.01-2 mJ per pulse with average-power of 0.1 to 0.5  
24 W. This energy level when focused into a spot size of  
25 (0.1-0.5) mm is sufficient to ablate the corneal  
26 tissue. This diode-pumped fifth-harmonic system  
27 provides the most compact refractive UV solid-state  
28 laser available today with the advantages of long  
29 lifetime, low maintenance, portability and absence of  
30 toxic gas in comparison with the excimer lasers  
31 currently used by other companies. Furthermore by  
32 using the fundamental wavelength at 1064 nm (or 1053  
33 or 1047 nm) or their second-harmonic (at 532, 524, or  
34 527 nm), intrastroma photokeratectomy procedure may be

1 performed by focusing the beam into the intrastroma  
2 area of the cornea. The laser presented in the  
3 present invention provide a compact, portable and  
4 low-cost IPK laser and has an advantage over the  
5 lasers used by other companies where the systems are  
6 currently more than five times heavier and are more  
7 costly.

8 In Fig. 3, a commercially available Ho:YAG (or  
9 Er:glass) or diode laser 35 (either flash-lamp or  
10 laser-diode pumped) is coupled by a fiber optic  
11 waveguide 36 with core diameter of (100-600) microns  
12 to a scanning device 37, in which the fundamental beam  
13 38 with a wavelength of 2.1 (or 1.54) or (1.9-2.5)  
14 microns which is collimated by a lens 40 and coupled  
15 to the scanning gavo 41 and focused by another lens 42  
16 onto the beam splitters 43 and 44, and finally  
17 delivered to a target (such as a patient's cornea) 45.  
18 The IR (2.1 microns) laser beam 38 is collinear with  
19 the aiming beam 46 (visible He-Ne or diode laser) and  
20 the patent corneal center is also defined by a  
21 commercial slit-lamp microscope station 47. The  
22 above-described apparatus offers the unique feature of  
23 non-contact laser thermokeratoplasty for precise  
24 coagulation in both spherical and astigmatic corneal  
25 power corrections with scanning patterns predetermined  
26 by a computer software hereinafter discussed. The  
27 focusing lens 28 may be motorized for varying the  
28 focal point and thus varying the coagulation cone size  
29 for optimal results. In the prior art of fiber-tip  
30 contact system, the precision of the coagulation zone  
31 and patterns are limited by doctors manual operation  
32 which is a much slower procedure than the computer  
33 controlled scanning device described in the present  
34 invention. The requirement of replacing the fiber-tip

1 after each operation is also a drawback of the prior  
2 art systems. The advantages of the present system  
3 includes: precision coagulation zone and spot size,  
4 flexible patterns for a variety of corrections, fast  
5 processing time and elimination of the need for  
6 fiber-tip replacement.

7 Still referring to FIG. 3, the basic laser 22 in  
8 accordance with the preferred embodiment of the  
9 present invention is a free-running or continuous-wave  
10 (CW) flash-lamp or diode-laser pumped Ho:YAG (at 2.1  
11 microns) or Er:glass (at 1.54 microns), or IR diode  
12 laser (1.9-2.5 microns) with average power of 0.5-5 W,  
13 pulse duration of 200-2,000 micro-seconds (if  
14 free-running). In the present invention, the IR  
15 wavelengths of 1.54 and 2.1 and (1.9-2.5) microns are  
16 chosen due to their strong tissue absorption which is  
17 required in the photo-coagulation processes. Similar  
18 lasing media of Ho:Tm:YAG and Ho:Tm:Cr:YAG is also  
19 included in the preferred embodiments of the present  
20 invention. The CW diode laser (1.9-2.5 microns) may  
21 be scanned in a faster rate than that of the free-  
22 running lasers.

23 Figs. 4A through 4E summarize the possible  
24 coagulation patterns suitable for both spherical and  
25 astigmatic corneal reshaping in the LTK procedures in  
26 a cornea 50. Fig. 4-A with coagulation zone (CZ) of 5  
27 to 9 mm and spot number (SN) of (8-16) provides  
28 hyperopic corrections of 1-6 diopters; Fig. 4-B has a  
29 coagulation zone of 1-3 mm suitable for myopic  
30 corrections; Fig. 4-C has radial coagulation zone and  
31 spot number of 16-32, suitable for spherical hyperopic  
32 correction; Fig. 4-D has a coagulation zone of 1-9 mm  
33 and spot number of 50-200, suitable for precise  
34 coagulation control to stabilize and reinforce the



1 collagen shrinkage tension; Fig. 4-E is designed for  
2 astigmatic change, where the coagulation patterns are  
3 chosen according to the corneal topography. By using  
4 the computer-controlled scanning, these patterns may  
5 be easily generated and predetermined according to the  
6 measured corneal topography of each patients. A  
7 combination of these patterns illustrated in Figs. 4-A  
8 to 4-E enables the treatment of patient's optical power  
9 correction in all aspects of myopia, hyperopia,  
10 astigmatism and their mixed vision disorder.  
11 Furthermore, laser parameters such as energy per  
12 pulse, spot size and scanning patterns also provide  
13 another degree of freedom for the laser  
14 thermokeratoplasty process which are not usually  
15 available in the prior art systems using the contact  
16 fiber-tip.

17 The appropriate parameters relating to Fig. 4A-B  
18 are: laser energy per pulse of 5-50 mJ for  
19 free-running mode (200-400 micro-second duration),  
20 beam spot size of (0.1-1) mm, laser repetition rate of  
21 5-30 Hz, coagulation zone of (1-10)mm, spot number of  
22 8-200 spots and fiber core diameter of 100-600  
23 microns, for a flash-lamp-pumped system. Also  
24 disclosed is the use of a diode-pumped Ho:YAG, either  
25 in a pulse-mode or continuous-wave (CW) mode. For a  
26 CW mode laser, energy of 10-100 mW is sufficient for  
27 coagulation when spot size of 0.05-0.5 mm is employed.  
28 In the diode-pumped system in CW mode or with a  
29 high-repetition-rate 20-100 Hz, a fast scanning  
30 enables completion of the coagulation procedures  
31 within 2-20 seconds depending upon the coagulation  
32 zone and spot number required. Fast scanning also  
33 provides a uniform collagen shrinkage unlike that of  
34 the prior art system using a manually operated

1 fiber-tip which normally takes 1 to 5 minutes to  
2 complete in a multiple coagulation zone and high spot  
3 number. It is difficult to use a manually operated  
4 fiber-tip to generate the precise patterns as  
5 illustrated in Fig. 4 which can be easily performed in  
6 the computer-controlled scanning device as disclosed  
7 in the present invention. The patient's eye motion and  
8 decentration is a problem for prior art systems, but  
9 it is not a critical factor in the fast scanning  
10 device described herein.

11 Referring to Fig. 5, a laser-assisted myopic  
12 keratomileusis (MKM) and hyperopic keratomileusis  
13 (HKM) can be performed either on the outer corneal  
14 surface 51 or on the inner surface 52 to reshape the  
15 resealed corneal tissue without materially effecting  
16 the Bowman's layer. The preferred lasers are  
17 described in Fig. 1 including the UV (193-220 nm) and  
18 IR (2.5-3.2 microns) lasers. The non-invasive  
19 laser-assisted procedure disclosed in the present  
20 invention has the advantages over the procedures of  
21 photorefractive keratectomy and laser  
22 thermokeratoplasty including being safer, more stable  
23 with a higher diopter change, and without materially  
24 affecting epithelium and Bowman's layer. In  
25 comparison with the conventional keratomileusis, the  
26 laser-assisted myopic keratomileusis and hyperopic  
27 keratomileusis do not require corneal freezing and can  
28 perform very high diopter change not available by  
29 radial keratotomy or photorefractive keratectomy.  
30 Laser-assisted corneal preshaping can also be employed  
31 for a donor cornea in the procedure currently  
32 performed by epikeratophakia. Details of conventional  
33 lamellar refractive surgery may be found in Leo D.

1 Bores, Refractive Eye Surgery (Blackwell Scientific  
2 Pub., 1993), Chapter 10.

3 Figs. 6A through 6D shows a nearly flat-top beam  
4 profile achieved by overlapping a series of laser  
5 beams, where the degree of overlap, 50%-80%, depends  
6 on the individual beam profiles which are not required  
7 to be flat-top. In the present invention, the  
8 preferred individual beam profile is either a 70%  
9 Gaussian or a symmetric profile. In the laboratory,  
10 I have demonstrated a smooth laser-ablated PMMA  
11 surface with zone diameter of 3-6 mm by overlapping a  
12 large number of pulses, 500 to 5,000, each one having  
13 a spot size of 0.8-1.2 mm. Moreover smooth transition  
14 among the ablation zones were achieved without the  
15 transition zone steps found in prior art systems using  
16 mechanical diaphragms. In addition to the myopic and  
17 hyperopic scanning patterns of 6B and 6C, one of the  
18 significant features of the present scanning device is  
19 that it can generate predetermined patterns based upon  
20 the corneal topography for astigmatism correction (see  
21 6D). Corneal scar may also be easily located by a  
22 topography and photoablated by a laser based on the  
23 computer-controlled scanning patterns. The preferred  
24 lasers for the procedures described in Fig. 6 are  
25 discussed in connection with Fig. 1.

26 Still referring to Fig. 6, the scanning schemes  
27 were tested by ablation on PMMA plasty. The computer  
28 software is based upon the mathematical model  
29 described earlier in equations 1 and 2 where the  
30 center ablation thickness was equally spaced to define  
31 the associate scanning diameters. Given the ablation  
32 thickness per pulse and per ablation layer (at a given  
33 scanning diameter), one may easily obtain the overall  
34 corneal surface ablation profile, (see equation (1)).

1 The number of required ablation layers is therefore  
2 proportional to the diopter change (D) and square of  
3 the ablation zone (W). The computer parameters  
4 designed in the present invention include: diopter  
5 change (D), optical zone diameter (W), and the degrees  
6 of overlap in both tangential (TD) and radial (RD)  
7 direction of the scan patterns as shown in Figs. 6A  
8 through 6D. Smooth PMMA surface ablation was achieved  
9 by optimization of laser spot size, energy and the  
10 overlap parameters of TD and RD. Experimental data  
11 indicates that larger overlap provides smoother  
12 surface ablation, however, longer ablation time is  
13 required for a given diopter change, laser energy and  
14 repetition rate (RR). Larger RR, 50-100 Hz, provides  
15 shorter ablation time which is typically in the range  
16 of (20-40) seconds for diopter changes of 2-8 in  
17 myopic treatment based upon my measurements. The  
18 prior art high-power excimer lasers with a typical RR  
19 of 5-15 Hz will be impossible to achieve the results  
20 described above even if they use the present scanning  
21 device.

22 Still referring to Figs. 6, using the UV lasers  
23 (193, 210 and 213 nm) I have achieved ablation depths  
24 of (20-40) microns by overlapping (2000-4000) laser  
25 pulses, which give an ablation depth of 0.05-0.1  
26 microns per pulse. The ablation depths are measured  
27 by 1a microsensor (made by Tencor Instruments) which  
28 has a resolution of about 0.5 microns or better.  
29 Ablation curves, ablation depth versus laser  
30 intensity, were obtained by varying the laser energy  
31 or the spot size. Given the ablation rate (ablation  
32 thickness per pulse), I am able to calibrate the  
33 number of pulses and the degree of beam overlap  
34 required to achieve the diopter change on the PMMA,

1 where the diopters of the ablated PMMA are measured by  
2 the standard lensmeter. In vitro measurement of  
3 corneal tissue ablation can be calibrated according to  
4 the comparison of the ablation rate between PMMA and  
5 tissue. For myopic and hyperopic corrections, I have  
6 used circular scanning patterns with beam overlap  
7 controlled by the tangential scanning speed and  
8 diameters of the adjoined circles. The preferred  
9 scanning scheme is from small circle to large circle.  
10 For example, given a laser spot size of 1 mm, a radial  
11 overlap of 50% will require the scanning circle to  
12 start from 1 mm diameter to 5 mm diameters with an  
13 increment of 0.5 mm for an optical zone of 5 mm.  
14 Furthermore, a tangential overlap of 50% requires the  
15 scanner to move at an angular speed of about 23  
16 degrees within the interval between each laser pulse.  
17 In my computer-controlled scanning device, software  
18 was developed to synchronize the laser repetition rate  
19 with the scanning gavo to control the above-described  
20 overlap patterns. In addition to the circular  
21 patterns described for myopic and hyperopic  
22 treatments, a linear scanning pattern may also be used  
23 in particular for the myopic and astigmatic  
24 corrections.

25 It is important to note that a uniform individual  
26 beam profile and energy stability of the laser, under  
27 the present scanning device, are not critical in  
28 achieving an overall uniform ablation zone whereas  
29 they are very critical for prior art systems using  
30 expanding iris devices. Given the ablation rate per  
31 overlapped circle, the overall diopter correction may  
32 be achieved by the appropriate increment in diameters  
33 of the expanding circles. Greater details of beam  
34

1 scanning and overlapping will be further discussed in  
2 connection with Figs. 9-11.

3 Referring to Figs. 7A and 7B, a laser radial  
4 keratectomy (LRK) performed by laser excision has  
5 advantages over the conventional diamond-knife radial  
6 keratotomy (RK) including higher predictability and  
7 reproducibility by precise control of the excision (or  
8 ablation) depth. Furthermore, using the scanning  
9 device of the present invention, laser radial  
10 keratotomy may be performed easily and rapidly with  
11 less dependance upon the surgeon's skill and  
12 experience. Corneal reshaping may be performed by  
13 controlling the laser parameters such as spot size,  
14 intensity, scanning speed, beam overlap, and the  
15 excision depth per pulse which typically ranges from  
16 0.2 to 0.5 microns. The excision depth precision of  
17 a laser is at least 10 times better than that of a  
18 knife. This "laser-knife" should be able to perform  
19 all the radial keratotomy procedures performed by a  
20 "diamond-knife" by using similar techniques to those  
21 introduced in the Book of Leo D. Bores, Refractive Eye  
22 Surgery, Chapters 8 and 9. Examples of laser radial  
23 keratotomy are shown in 7A for myopia (radial-cut) and  
24 7B for astigmatism (T-cut). The preferred lasers for  
25 laser radial keratotomy include the lasers described  
26 in Fig. 1.

27 Referring to Figs. 8A and 8D, the ablation  
28 patterns suitable for refractive procedures may be  
29 generated by using coated windows such as UV (or IR)  
30 grade fused silica, MgF, BaF or sapphire (when an IR  
31 laser is used), with preferred thickness of (0.5-2) mm  
32 and diameter of (8-15) mm. Referring to Fig. 8A,  
33 scanning laser beams 53 (at wavelength of UV or IR)  
34 with circular scanning pattern to deliver uniform (or

1 constant) laser energy over the coated window 44 with  
2 coating specification (at UV or IR wavelength)  
3 according to the profile on the corneal tissue 55 (or  
4 PMMA surface) will also achieve the same pattern  
5 described by equation (1). Figs. 8B and 8C show the  
6 reflection profiles of the coated windows for myopia,  
7 hyperopia and astigmatism, respectively, based on  
8 predetermined diopter changes. These coated windows  
9 disclosed in the present invention can be reused for  
10 cost effectiveness and has an advantage over the prior  
11 art system using the disposable mask which is costly  
12 and is difficult to provide reproducible results due  
13 to the non-uniform transmission or ablation properties  
14 of the mask.

15 Greater detail of the features of the present  
16 invention regarding beam overlap, scanning and  
17 orientation in order to achieve uniform ablation  
18 profiles to meet the clinical requirements of corneal  
19 reshaping are demonstrated as follows. The actually  
20 measured PMMA profiles were generated from the  
21 Microsensor (made by TENCOR INSTRUMENTS, INC.) using  
22 our ArF laser (the Compak-200 Mini-Excimer system,  
23 made by LaserSight, Inc.) having laser parameters of:  
24 (2-4 mJ) energy at the output window, operated at  
25 (50-200) Hz, with the beam focused onto the corneal  
26 surface at a spot size of about (0.2-1.2) mm, with  
27 energy per pulse of (0.5-1.5) mJ, tunable by a coated  
28 MgF window.

29 Referring to Fig. 9A, we show the schematic of  
30 the motion of the scanning beam with a spot size of 1  
31 mm in this example. Beam overlap function(L) is  
32 defined by the beam displacement parameters of dx and  
33 dy (in x and y direction, respectively, on the corneal  
34 plane) adjustable by the computer controlled software,

1 where  $L_x = 1 - dx/R$  and  $L_y = 1 - dy/R$ , where  $R$  is the beam  
2 diameter. The degrees of smoothness (DS) of the  
3 ablated PMMA surface (a plastic sheet which has been  
4 commonly used for the calibration of UV laser ablation  
5 on corneal tissue) is governed by the degrees of  
6 overlap function  $L = L_x + L_y$ . Greater DS can be  
7 performed by using greater  $L$ , which, however, will  
8 also cause a slower procedure speed ( $v$ ), at a given  
9 laser average-power ( $p$ ), beam spot size ( $R$ ) and  
10 energy per pulse ( $E$ ). Desired procedure time of 20 to  
11 50 seconds are typical for patient diopter corrections  
12 (myopic) of  $D = -3$  to  $-10$ , where patient centration is  
13 conducted by a visible fixation light for the patient  
14 to look at without eye movement. Including some of  
15 the compensation from the recovered epithelium filling  
16 on the ablated corneal surface, the roughness of the  
17 corneal tissue, calibrated by the PMMA surface, should  
18 be within the range of (0.2-2) microns. Therefore, we  
19 are optimizing the parameters of  $dx$ ,  $dy$ ,  $L$ ,  $p$ ,  $E$  and  $R$   
20 in order to achieve the above-described clinical  
21 requirements.

22 Referring to Fig. 9B, a comparison is shown to  
23 demonstrate the degrees of smoothness of the ablated  
24 PMMA at two sets of displacements: curve A ( $dx = dy = 0.5$   
25 mm) and curve B ( $dx = 0.5$  mm,  $dy = 0.3$  mm). These PMMA  
26 profiles were generated from a Microsensor scanned  
27 along the  $y$  direction to show the difference in  
28 smoothness caused by the difference in  $dy$  values (at  
29 a fixed  $dx$  value). It is clearly demonstrated by  
30 comparing Curves A and B that a smoother surface is  
31 generated with a smaller displacement ( $dy = 0.3$  mm), or  
32 larger beam overlap  $L_x = 70\%$ . In this particular  
33 example, the basic beam profile is worse than a 50%  
34 Gaussian and actually has a three-lobe structure which



1 is typical in an ArF excimer laser. Even under this  
2 poor beam uniformity condition, we are still able to  
3 obtain very uniform overall ablated areas of (2-9) mm  
4 in diameter, as shown in Fig. 9B (curve B) with  
5 surface roughness less than 1 microns (vs. about 10  
6 microns in curve A), when a set of appropriate beam  
7 overlap parameters are used. Smaller dx and dy will  
8 further improve smoothness, which, however, may take  
9 a longer operation time. As shown in above example  
10 (using dx=0.5 mm and dy=0.3 mm), only 30 seconds is  
11 needed for a D=-4 diopter correction with enough  
12 smoothness of the PMMA surface, where I used a pulse  
13 energy of 0.9 mJ (on the PMMA surface), with the  
14 system operated at 100 Hz in this example.

15 In addition to the overlap function, I have been  
16 able to further improve the beam uniformity by the  
17 beam orientation method as follows. As shown in Fig.  
18 10A, I used linear scan patterns for multi-layer  
19 ablation on a PMMA sheet, where parameters of E=0.9  
20 mJ, spot size of 1 mm, dx=dy=0.5 mm were used. In one  
21 case, I repeated the linear scan pattern along the  
22 x-direction, or rotation angle (A)= zero, for about 25  
23 times (layers). To see the improvement due to pattern  
24 orientation, I tried the second case by rotating the  
25 linear-scan angle (A) by about 65 degrees in each  
26 successive scan layers. An angle A=65 degrees was  
27 chosen in this particular example to randomize the  
28 basic beam structure (having a non-uniform profile)  
29 and to achieve the uniform overall ablation. This  
30 averaging procedure by beam orientation will largely  
31 reduce the potential roughness caused by the basic  
32 beam structure, noting that rotation angles, such as  
33 20, 30, 60 or 120 degrees (in which 360 degrees can be  
34 divided into integers), should be avoided to prevent

1 repeated patterns after a few rotation layers. A  
2 larger angle(A) is chosen for smaller diopter  
3 corrections and vice versa for the best results. This  
4 is to make sure that enough beam randomization is  
5 performed for various diopter corrections which are  
6 proportional to the numbers of scanned layers.  
7 Comparisons are shown in Fig. 10B for A=0 (nonrotated  
8 case, curve A) and for A=65 (rotated case, curve B),  
9 where  $dx=dy=0.5$  mm were used in both cases.  
10 Significant smoothness of ablated PMMA was achieved in  
11 the rotated case (curve B) even when a large  
12 displacement of  $dy=0.5$  mm was used, compared to curve  
13 B in Fig. 10B and curve A in Fig. 9B. The larger  
14 displacement, or smaller overlap results in a faster  
15 procedure, however, this results in a loss of  
16 smoothness if beam rotation is not used. Using the  
17 above-described techniques, I am able to generate the  
18 predetermined ablation profiles corresponding to  
19 various refractive corrections such as myopic,  
20 hyperopic and astigmatic with clinically acceptable  
21 tissue smoothness and procedures times requirement.

22 Referring to Fig. 11, an example for myopic  
23 correction is shown. Fig. 11A shows the schematic of  
24 rotated ablated areas with increasing diameters (from  
25 about 0.5 to 6 mm) governed by Equation (1), where a  
26 typical number of layers (or scanned areas at various  
27 diameters) of 25 is needed for a -5 diopter  
28 correction. For an optical zone of 5 mm, this  
29 represents an ablation rate of about 2 microns in  
30 corneal tissue in each layer, where a pulse energy of  
31 about 0.9 mJ at spot size of 1 mm and repetition rate  
32 of 100 Hz is used. For smaller diopter corrections,  
33 a smaller energy (0.6-0.8 mJ), or smaller ablation  
34 rate (0.5-1.0 microns) is desired for smoother and

1 more accurate results. Moreover, a smaller spot size  
2 of (0.1-0.5 mm) may be used for better control of the  
3 ablation profile (with greater accuracy), but a faster  
4 laser repetition rate larger than 500 Hz would be  
5 required for a reasonable procedure speed of (20-50)  
6 seconds to cover (-3 to -10) diopter corrections. In  
7 this situation the diode pumped UV solid state laser  
8 described earlier will be a better candidate than the  
9 Excimer laser. Fig. 11B shows the PMMA ablation  
10 profile measured from a Microsensor using the  
11 techniques shown in Fig. 11A, where an ablation zone  
12 size of about 5 mm with center depth of about 16  
13 microns were shown. I believe that the PMMA profiles  
14 shown in Figs. 9 through 11 represent, for the first  
15 time, the novel features of the techniques disclosed  
16 in the present invention. Some of the prior art has  
17 never demonstrated the actual ablation data, although  
18 a simple concept of beam scanning has been proposed.  
19 The comparisons in Figures 9 and 10 have demonstrated  
20 that the prior techniques as set forth in the  
21 background hereto would never achieve the smooth  
22 surface as shown here. In addition, given the laser  
23 parameters proposed in the present invention of  
24 low-energy (2-4 mJ) with nonuniform basic beam profile  
25 and without using mechanical beam re-shaping, it is  
26 impossible for the prior art to achieve clinically  
27 meaningful results. A high-power laser of 100-300 mJ  
28 with a complex means of beam uniformity is always  
29 required in the prior art patents.

30 The method disclosed in the present invention  
31 combines beam scanning, overlapping and pattern  
32 rotation (randomization) provides a powerful yet  
33 simple technique for optimal results of laser  
34 refractive surgery which involves both clinical

1 aspects (ablation diopter, ablation optical zone,  
2 smoothness, patient centration and operation speed)  
3 and engineering aspects (beam profile, uniformity,  
4 stability, energy, spot size and delivery systems).

5 It is worth emphasizing that the concept of  
6 achieving a smooth ablation surface by using the  
7 randomly rotated scanning pattern as disclosed in the  
8 present invention would not be demonstrated if the  
9 microsensor were not used to measure the PMMA  
10 profiles. I have preformed hundreds of PMMA profile  
11 analyses at various laser parameters together with the  
12 theoretical model presented in equations (1) - (5) are  
13 the key factors behind the present process.  
14 Furthermore, the refractive correction profile,  
15 governed by equation (1) would be very difficult to  
16 justify after the scanning method is applied to the  
17 target (PMMA and corneal tissue) if the microsensor is  
18 not available to the user. The PMMA data presented in  
19 the present invention have also been employed on  
20 corneas, where hundreds of patient's have been treated  
21 by the Compak-200, Mini-Excimer with predictable power  
22 corrections and smooth tissue ablation. Clinical  
23 results are to be presented in ophthalmology  
24 conferences.

25 While the invention has been shown and described  
26 with reference to the preferred embodiments thereof,  
27 it will be understood by those skilled in the art that  
28 the foregoing and other changes and variations in form  
29 and detail may be made therein without departing from  
30 the spirit, scope and teaching to the invention.  
31 Accordingly, the method and apparatus, the ophthalmic  
32 applications herein disclosed are to be considered  
33 merely as illustrative and the invention is to be  
34 limited only as set forth in the claims.

CLAIMS:

I claim:

- 1           1.    A non-contact scanning laser system for  
2   performing corneal refractive surgery by reshaping a  
3   portion of a corneal surface comprising:
  - 4           a laser (10, 35) having a pulsed output beam of  
5   predetermined ultraviolet wavelength and having an  
6   energy level less than 10 mJ/pulse;
  - 7           a scanning mechanism (12, 37) for scanning said  
8   selected laser output beam (11, 38), said scanning  
9   mechanism (12, 37) including a galvanometer scanning  
10   mechanism for controlling said laser beam into an  
11   overlapping pattern of adjacent pulses;
  - 12          a coupling mechanism (15, 44) coupling said laser  
13   beam (11, 38) to a scanning device (12, 37) for  
14   scanning said laser beam over a predetermined surface  
15   area;
  - 16          focusing optics for scanning said laser beam  
17   (11, 38) onto a corneal surface to a predetermined  
18   generally fixed spot size;
  - 19          alignment mechanism (17, 43) for aligning the  
20   center of the said scanning laser beam onto the  
21   patient's eye corneal surface with a visible aiming  
22   beam (18);
  - 23          controlling means (23) for controlling the  
24   scanning mechanism (12, 37) to deliver the scanning  
25   laser beam (11, 38) in a predetermined overlapping  
26   pattern onto a plurality of positions on the corneal  
27   surface to photoablate or photocoagulate corneal  
28   tissue to remove from .05 to .5 microns of corneal  
29   tissue per pulse with overlapped pulses to remove

30 tissue to a desired depth, whereby a low power non-  
31 contact scanning laser system improves corneal  
32 reshaping surgery.

1           2. A non-contact scanning laser system in  
2 accordance with claim 1 in which the laser (10, 35) is  
3 a diode-pumped UV laser having an output wavelength  
4 between 193 and 220 nanometers, and energy per pulse  
5 of 0.01 to 5 mJ/pulse, a repetition rate of between 1  
6 Hz and 10 KHz, and a pulse duration between 0.1  
7 picoseconds to 50 nanoseconds and a focused spot size  
8 of (0.05-1.5) mm on the corneal surface.

1           3. A non-contact scanning laser system in  
2 accordance with claim 1 in which the laser (10, 35) is  
3 a flash lamp pumped UV laser having an output  
4 wavelength between 193 and 220 nanometers, and energy  
5 per pulse of 0.1 to 10 mJ/pulse, a repetition rate of  
6 between 1 Hz and 10 KHz, and a pulse duration between  
7 0.1 picoseconds to 50 nanoseconds and a focused spot  
8 size of (0.05-1.5) mm on the corneal surface.

1           4. A non-contact scanning laser system in  
2 accordance with claim 1 in which a laser (10, 35) is  
3 an argon fluoride excimer laser having an output  
4 wavelength of 193 nanometers, energy per pulse of 0.5  
5 to 10 mJ/pulse and a focused generally fixed spot size  
6 of between 0.2 to 2 mm on the corneal surface, and a  
7 repetition rate of between 1 to 1,000 Hz, and pulse  
8 duration of between 1 to 50 nanoseconds.

1           5.     A non-contact scanning laser system in  
2     accordance with claim 1 in which the laser (10, 35) is  
3     a free-running Ho:YAG laser having an output  
4     wavelength of about 2.1 microns at an average power of  
5     between 0.5-5 watts and a focused generally fixed spot  
6     size of between 0.1-1 mm.

1           6.     A non-contact scanning laser system in  
2     accordance with claim 1 in which the laser (10, 35) is  
3     a free-running Er:glass laser having an output  
4     wavelength of about 1.54 microns at an average power  
5     of between 0.5-5 watts with a focused generally fixed  
6     spot size of between 0.1-1 mm.

1           7.     A non-contact scanning laser system in  
2     accordance with claim 1 in which the laser (10, 35) is  
3     a free-running Er:glass laser having an output  
4     wavelength of between 1.9 to 2.5 microns at a power of  
5     between 0.5-5 watts and a focused generally fixed  
6     spot size of between 0.1-1 mm.

1           8.     A non-contact scanning laser system in  
2     accordance with claim 1 in which the laser (10, 35) is  
3     a Q-switched Er:YAG laser having an output wavelength  
4     of 2.94 microns, and a pulse duration of between 50 to  
5     400 nanoseconds, with an energy per pulse of between  
6     50-500 mJ and a repetition rate of between 1 and 200  
7     Hz with a focused generally fixed spot size of between  
8     0.2-2 mm.

1           9. A non-contact scanning laser system in  
2 accordance with claim 1 in which the laser (10, 35) is  
3 an ultra-short pulsed laser having an output  
4 wavelength of between 750 to 1100 nanometers, energy  
5 per pulse of between 0.01 to 100 microjoules, and a  
6 repetition rate of between 0.01 to 100 MHz, and pulse  
7 duration of between 0.05-10 picoseconds and a focused  
8 generally fixed spot size of between 0.05-0.5 mm.

1           10. A non-contact scanning laser system in  
2 accordance with claim 1 in which the laser (10, 35) is  
3 an OPO mid-IR laser having an output of 2.5-3.2  
4 microns, a pulse duration of between 1-40 nanoseconds  
5 and energy per pulse of between 0.1 to 10 mJ, and a  
6 repetition rate of between 10 and 5,000 Hz and a  
7 focused generally fixed spot size on the corneal  
8 surface of between 0.1 - 2 mm.

1           11. A non-contact scanning laser system in  
2 accordance with claim 1 in which a focusing lens (14,  
3 42) for delivering said laser beam (11, 38) is highly  
4 transparent to the said laser beam and has a focal  
5 length of (50-1500) mm for focusing the laser source  
6 onto a generally fixed spot size of 0.05-2 mm on a  
7 predetermined position on the corneal surface.

1           12. A non-contact scanning laser system in  
2 accordance with claim 1 in which said controlling  
3 means (23) controls said scanning mechanism (12, 37)  
4 to scan a pattern of radial aligned spots (Figures 4A,  
5 4C, 7A) using a laser beam capable of photocoagulation  
6 corneal tissue.



1           13.     A non-contact scanning laser system in  
2     accordance with claim 1 in which said controlling  
3     means (23) controls said scanning mechanism (12, 37)  
4     to scan a pattern of concentric generally fixed spots  
5     (Figures 4A, 4B, 4C, 4D, 6B, 6C) using a laser beam  
6     capable of photocoagulating corneal tissue.

1           14.     A non-contact scanning laser system in  
2     accordance with claim 1 in which said controlling  
3     means (23) controls said scanning to scan a pattern of  
4     generally fixed area ring spots (Figures 4A-4E & 6A-  
5     6D) using a laser beam capable of photocoagulating  
6     corneal tissues.

1           15.     A non-contact scanning laser system in  
2     accordance with claim 1 in which said controlling  
3     means (23) controls said scanning to scan a pattern of  
4     overlapping generally fixed area ring spots (Figures  
5     6A-6D) using a laser beam capable of photoablating  
6     corneal tissue for myopic correction.

1           16.     A non-contact scanning laser system in  
2     accordance with claim 1 in which said controlling  
3     means (23) controls said scanning to scan a pattern of  
4     overlapping generally fixed area ring spots (Figures  
5     6A-6D) using a laser beam capable of photoablating the  
6     corneal tissue for hyperopic correction.

1           17.     A non-contact scanning laser system in  
2 accordance with claim 1 in which said controlling  
3 means (23) controls said scanning to scan a pattern of  
4 overlapping circles of fixed area (Figures 6A-6D)  
5 using a laser beam capable of photoablating the  
6 corneal tissue for astigmatic correction.

1           18.     A non-contact scanning laser system in  
2 accordance with claim 1 in which said controlling  
3 means (23) controls said scanning to scan a pattern of  
4 radial aligned slits (Figures 7A & 7B) of fixed area  
5 using a laser beam capable of photoablating corneal  
6 tissue for laser radial keratectomy.

1           19.     A non-contact scanning laser system in  
2 accordance with claim 1 in which said controlling  
3 means (23) controls said scanning which has a circular  
4 scanning pattern to deliver uniform laser energy over  
5 a coated window (44) positioning near the corneal  
6 surface.

1           20.     A non-contact scanning laser system in  
2 accordance with claim 19 in which said scanning  
3 mechanism (12, 37) scans a coated window (44) having  
4 a predetermined coating to direct said laser beam  
5 therethrough and to photoablate the corneal surface to  
6 meet a predetermined profile for refractive  
7 corrections.

1           21.     A non-contact scanning laser system in  
2     accordance with claim 19 in which said scanning  
3     mechanism (12, 37) scans through a coated window (44)  
4     made of materials transparent to a UV laser having an  
5     output beam of (193-215) nm.

1           22.     A non-contact scanning laser system in  
2     accordance with claim 19 in which said scanning  
3     mechanism (12, 37) scans through a coated window (44)  
4     made of materials highly transparent to an IR laser  
5     having an output beam of (2.5-3.2) microns.

1           23.     A non-contact scanning laser system in  
2     accordance with claim 1 in which said scanning  
3     mechanism (12, 37) scans a uniform scanned pattern  
4     (Figures 9A & 9B) with a spatial overlap of 50-80%  
5     and beam orientation whereby the initial beam profile  
6     uniformity is not critical.

1/5

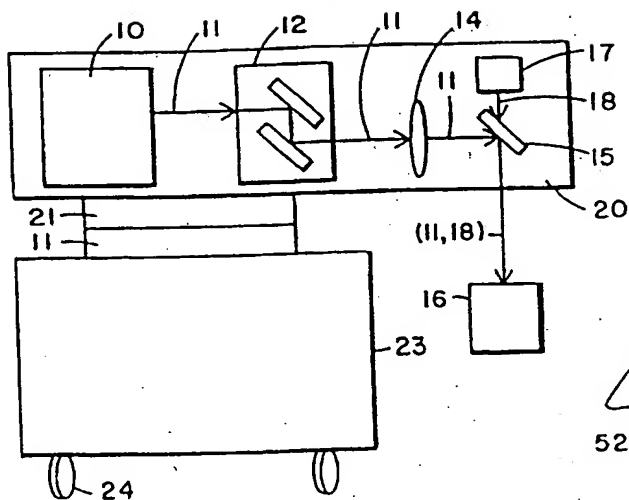


FIG. 1

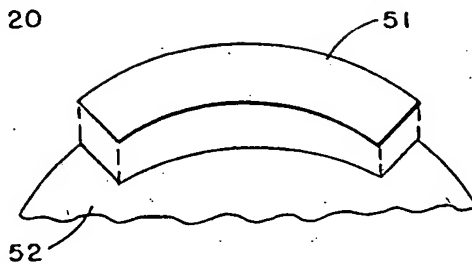


FIG. 5A

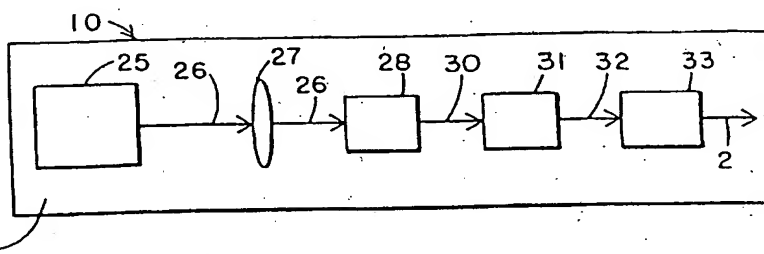


FIG. 2

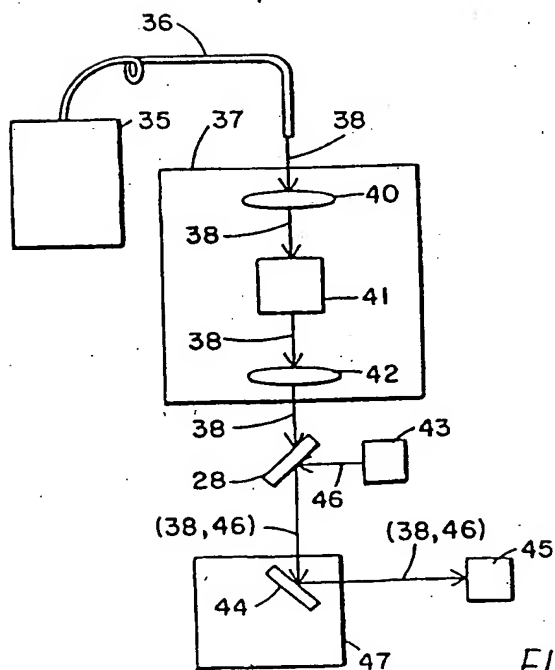


FIG. 3

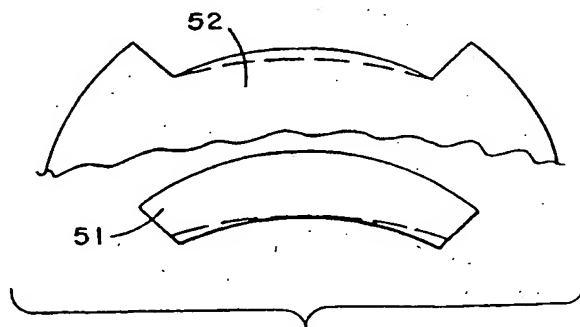


FIG. 5B

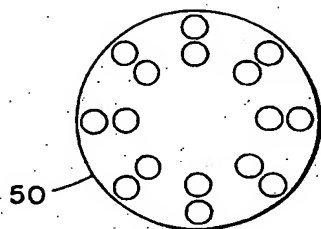


FIG. 4A

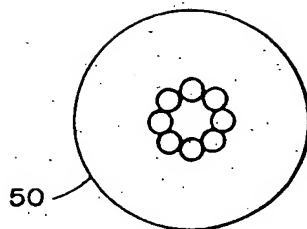


FIG. 4B

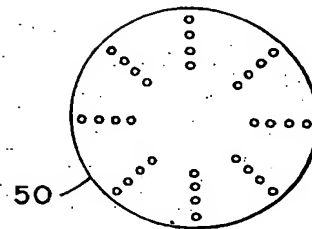


FIG. 4C

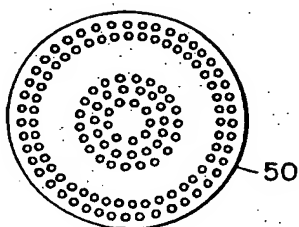


FIG. 4D

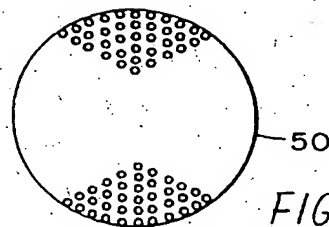


FIG. 4E

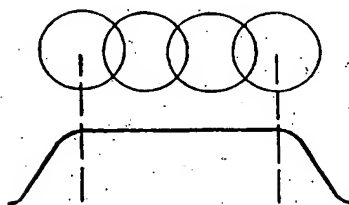


FIG. 6A

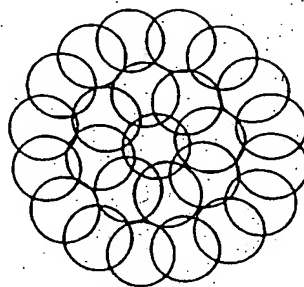


FIG. 6B

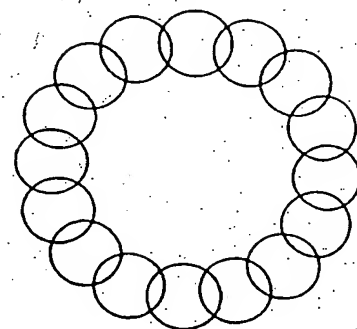


FIG. 6C

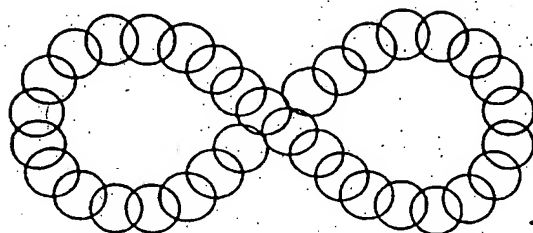


FIG. 6D

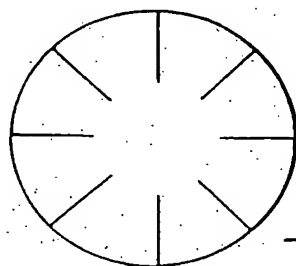


FIG. 7A

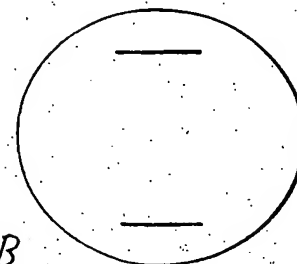


FIG. 7B

3/5

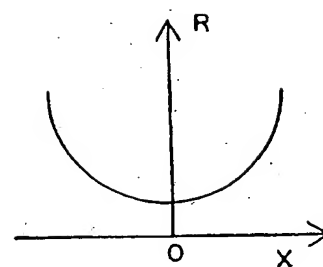
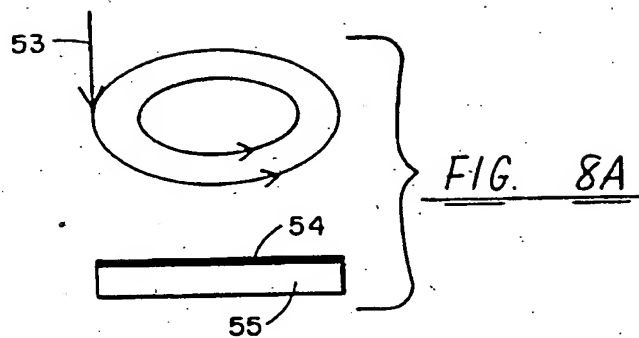


FIG. 8B

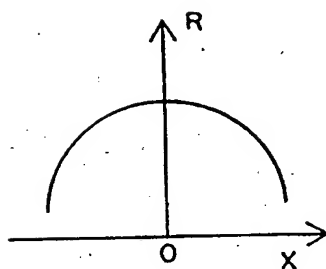


FIG. 8C

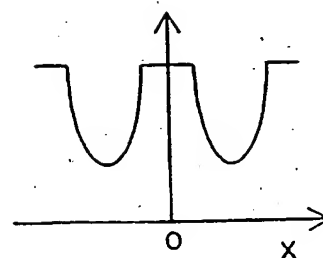
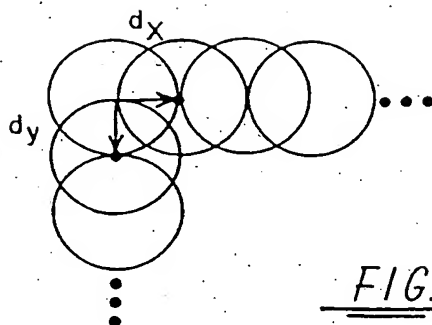
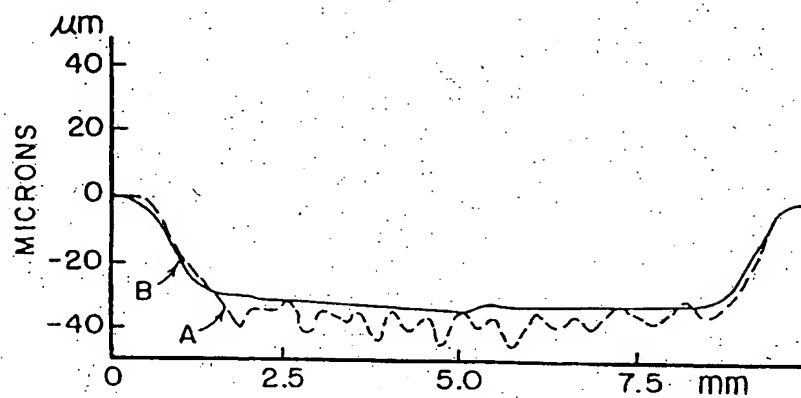
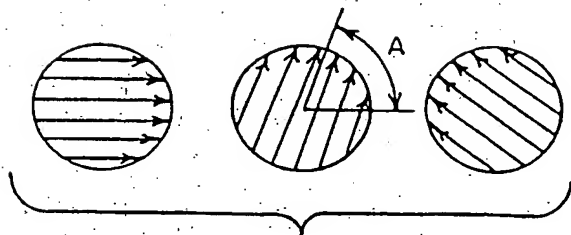
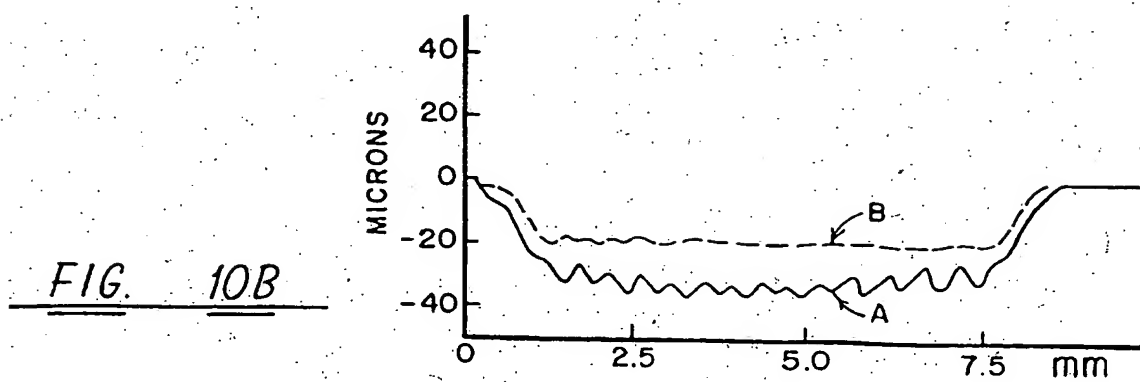


FIG. 8D

4/5

FIG. 9AFIG. 9BFIG. 10AFIG. 10B

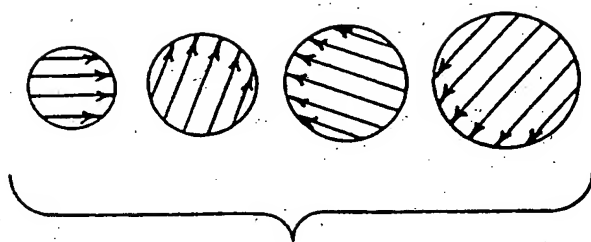


FIG. 11A

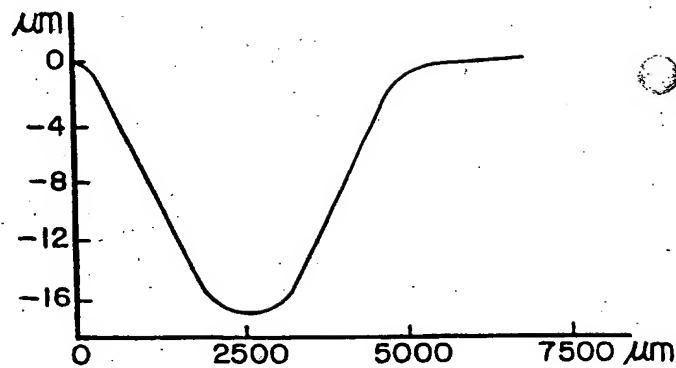


FIG. 11B



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/02663

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/02

US CL :606/005

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/3-6, 10-12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,718,418 (L'ESPERANCE, JR.) 12 January 1988, see whole document.	1-23
A	US, A, 4,729,372 (L'ESPERANCE, JR.) 08 March 1988, see whole document.	1-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

30 MAY 1996

Date of mailing of the international search report

08 AUG 1996

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3590

Authorized officer

MICHAEL PEFFLEY

Telephone No. (703) 308-4305

**THIS PAGE BLANK (USPT**